



RECEIVED  
APR 09 2003  
TECH CENTER 1600/2306  
PTO/SB/21 (08-00)

Please type a plus sign inside this box

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	09/909,544	
	Filing Date	July 19, 2001	
	First Named Inventor	Tom F. Lue	
	Group Art Unit	1636	
	Examiner Name	Celine X. Qian	
Total Number of Pages in This Submission	4	Attorney Docket Number	220022001600

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form  <input type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment/Reply  <input type="checkbox"/> After Final  <input checked="" type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application)  <input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below) Return Postcard
<div>Remarks</div> <div> <b>25225</b> PATENT, TRADEMARK OFFICE</div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual Name	MORRISON & FOERSTER LLP Peng Chen - 43,543
Signature	
Date	March 31, 2003

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date shown below.	
Dated: 3-31-03	Signature:  (Rhea Amid)

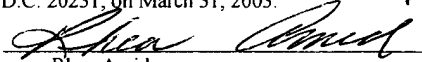


PATENT  
Docket No. 220022001600

RECEIVED  
APR 09 2003  
TECH CENTER 1600/2900

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:  
Assistant Commissioner for Patents, Washington, D.C. 20231, on March 31, 2003.

  
Rhea Amid

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Tom F. LUE, et al.

Serial No.: 09/909,544

Filing Date: July 19, 2001

For: METHODS AND COMPOSITIONS FOR  
PREVENTING AND TREATING MALE  
ERECTILE DYSFUNCTION AND  
FEMALE SEXUAL AROUSAL  
DISORDER

Examiner: Celine X. Qian

Group Art Unit: 1636

DECLARATION OF TOM F. LUE PURSUANT TO 37 C.F.R § 1.132

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, Tom F. Lue, in my individual capacity, hereby declares as follows:

1. I am one of the co-inventors of the above-referenced patent application, and am familiar with the contents thereof.

Bakircioglu

2. I have reviewed the publication entitled “The effect of adeno-associated virus-mediated brain-derived neurotrophic factor in an animal model for neurogenic impotence,” published in *Journal of Urology*, Vol. 163, No. 4 Suppl., pp. 198 (April, 2000) (Bakircioglu), and cited by the Examiner, for which I am a co-author. The publication was cited by the Examiner as prior art against the application under 35 U.S.C. § 102(a).

3. The publication cited describes work that is encompassed by this patent application and its parent applications. The co-authors, Bakircioglu, M.E., Wefer, J., Sievert, KD and Fan, P., named in the publication were not involved in the conception of the subject matter of the presently claimed invention. Moreover, these co-authors worked under my and other co-inventors’ direction performing work that led to the invention, but did not make an inventive contribution to the subject matter of the presently claimed invention.

Treatment of erectile dysfunction with vascular changes by BDNF

4. My co-inventors and I have performed, or have directed others to perform, experiments that show that a high fat diet caused erectile dysfunction with accompanying neurological and vascular changes. The changes include less nerve content, fewer endothelial cells and lighter smooth muscle content, hypermyelination and severe atrophy of axons, a remarkable decrease in the number and size of nonmyelinated axons, disarray of the smooth muscle cells with scant myofilaments and foamy cytoplasm and denuded endothelial lining of the sinusoids covered by numerous platelets (*See Exhibit 1, Gholami et al., “The Effect of Vascular Endothelial Growth Factor and Adeno-Associated Virus Mediated Brian Derived Neurotrophic Factor on Neurogenic and Vasculogenic Erectile Dysfunction Induced by Hyperlipidemia,” to be published in J. Urology (2003).*). Our experiments also show that treatment with BDNF, *e.g.*, AAV-BDNF, alleviates, at least partially, these changes.

Prevention of erectile dysfunction by BDNF treatment

5. My co-inventors and I have performed, or have directed others to perform, experiments that show that, after nerve crush, BDNF/VEGF treatment can prevent and facilitate regeneration of nNOS containing neurons in the major pelvic ganglia, dorsal never and intracavernous tissue (*See Exhibit 2. Bochinski et al., "The Effect of Vascular Endothelial Growth Factor and Brian Derived Neurotrophic Factor on Cavernous Nerve Regeneration in a Nerve-Crush Rat Model," manuscript submitted to British Journal of Urology*). This result indicates that BDNF can have preventive, as well as therapeutic, effect to the erectile dysfunction.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

March 17, 2003

Date



Tom F. Lue